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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/511,314

05/17/2005

David Wallach

WALLACH33

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1444 7590 09/29/2009
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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

09/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|--|--------------------------------------|---------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 10/511,314 | Applicant(s) WALLACH ET AL. | |
| | Examiner SHERIDAN SWOPE | Art Unit 1652 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: 69,70,75,82,83,85-88,90,91 and 102-105.
 Claim(s) rejected: 69, 70, 75, 82, 83, 85-88, 90, 91, and 102-105.
 Claim(s) withdrawn from consideration: 20,25,72,84 and 89.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652

Continuation of 11. does NOT place the application in condition for allowance because:

No claim amendments have been filed.

Regarding Applicants' remarks, the following comments are made.

Regarding rejection under 35 USC 112/enableness:

(A) Applicants argue that the Office has misrepresented the binding of SEQ ID NO: 18 to full-length cgc; +/- means weak binding.

It is acknowledged that +/- means weak binding.

(B) The specification shows the binding of a NIK c-terminus peptide (NIK624-947) (SEQ ID NO: 19) has '++++' binding with full-length common gamma chain and SEQ ID NO: 19 comprises SEQ ID NO: 18.

Demonstration that a protein has binding activity does not allow the skilled artisan to deduce that, more likely than not, a fragment of said protein has the same binding activity.

(C) Figure 5, clearly shows that the NIK c-terminus (comprising SEQ ID NO: 18) inhibits common gamma chain induced enhancement of NIK function.

Demonstration that a protein inhibits an enzymatic activity does not allow the skilled artisan to deduce that, more likely than not, a fragment of said protein inhibits a binding activity.

(D) SEQ ID NO: 18 is actually the minimal common gamma chain binding region in NIK that was identified by deletion analysis.

Demonstration that deletion of a peptide region in a protein alters the protein's function is not sufficient to convince the skilled artisan that, more likely than not, said peptide alone has the desired function.

(E) Modulation of NIK-common gamma chain pathway is relevant for only those diseases which involve defects in NF-KB activation induced by specific interleukins.

The claims are not limited to diseases which involve defects in NF-KB activation induced by specific interleukins.

(F) It is presumed that the previous response overcame the part of the rejection with respect to the scope of the polypeptide to be administered.

The skilled artisan would be enabled for making the genus of polypeptides that are (i) a fragment of SEQ ID NO: 18 or (ii) all variants of SEQ ID NO: 18 having at least 90% identity. The type and function of the derivatization encompassed is not recited.

Regarding rejection under 35 USC 112/written description:

Applicants provide the same arguments set forth above (A)-(F).